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ONYX PHARMACEUTICALS, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ONYX PHARMACEUTICALS, INC.,

Plaintiff,

v.

BAYER CORPORATION, BAYER AG, BAYER HEALTHCARE LLC, AND BAYER SCHERING PHARMA AG,

Defendants.

Case No. C 09-2145 (MHP)

JOINT CASE MANAGEMENT CONFERENCE STATEMENT, RULE 26(f) REPORT, AND PROPOSED ORDER

Case Management Conference:
Date: August 31, 2009
Time: 4:00 p.m.

Pursuant to this Court's Civil Local Rules ("Civ. L.R.") 16-7 and 18, the parties jointly submit this Case Management Statement, Rule 26(f) Report, and Proposed Order. Each party certifies that its lead trial counsel who will try this case met and conferred for the preparation of this Statement as required by Civ. L.R. 16-4.

The parties make the following representations and recommendations:

A. JOINT STATEMENT OF FACTS AND EVENTS UNDERLYING THE ACTION

Onyx and Miles, Inc., a predecessor to Bayer Corporation, entered into a Collaboration Agreement dated April 22, 1994. Under that agreement, Onyx and Miles agreed to work together to perform research towards identifying and investigating substances that inhibit components of a biochemical pathway involved in cancer, called the "Ras pathway" and develop and commercialize substances identified in such process as pharmaceutical products for the treatment of cancer. The agreement makes chemical compounds that satisfy the recited definitions for "Collaboration Compound" and "Post-Collaboration Compound" subject to potential collaborative development and/or potential profit-sharing. The agreement and its subsequent amendments are referred to hereinafter as the "Collaboration Agreement." According to Bayer, the right, title, and interest in and to the Collaboration Agreement were assigned to Bayer Healthcare LLC in 2007.

Also on April 22, 1994, Miles and its parent company, Bayer AG, entered into a Letter Agreement. Bayer AG agreed that to the extent it or any of its affiliates performed Miles' obligations under the Collaboration Agreement, they would do so in accordance with the Collaboration Agreement's terms. According to Bayer AG, the Letter Agreement was transferred to Bayer Schering Pharma AG.

The parties' collaboration yielded the compound sorafenib, which is marketed as "Nexavar." Sorafenib has been FDA-approved for treatment of two cancer indications and studies are in progress for additional indications. Sorafenib has generated total sales in excess of $1 billion to date.

Independent of Onyx, Bayer is currently conducting clinical trials for a compound it refers to as "DAST." Onyx alleges that in spring of 2009 it learned that the "DAST" compound has a chemical structure that is the same as the sorafenib/Nexavar structure, except that a fluorine atom is substituted for a hydrogen atom at one location. For this reason, Onyx refers to this compound as "fluoro-sorafenib."

Bayer asserts that the World Health Organization has now given the "DAST" compound the official name regorafenib. Although Onyx believes that the term fluoro-sorafenib more

accurately describes the compound's chemical structure, it has agreed that this CMC Statement shall refer to the compound as regorafenib.

Onyx contends that the regorafenib compound is a Collaboration Compound under the Collaboration Agreement. Onyx further believes that Bayer's development of this compound is undermining the value of sorafenib and that, through this and other actions, Bayer has breached Article 3.6 of the Collaboration Agreement.

Bayer asserts that the regorafenib compound is not a Collaboration Compound or Post-Collaboration Compound under the Collaboration Agreement because, among other things, it was first synthesized and tested after the defined periods for those terms in the Collaboration Agreement. Bayer also denies that it has violated Article 3.6.

After the parties attempted unsuccessfully to resolve their disagreement, Onyx brought this action for breach of contract, breach of the implied covenant of good faith and fair dealing, breach of fiduciary duty, and declaratory relief.

B. PRINCIPAL ISSUES

1. **The principal factual issues that the parties dispute are:**

   a. Whether the regorafenib compound is a Collaboration Compound under the Collaboration Agreement.

   b. Whether defendants breached their obligations in the Collaboration Agreement by their independent development of regorafenib.

   c. Whether defendants breached Article 3.6 of the Collaboration Agreement.

   d. Whether defendants breached an implied covenant of good faith and fair dealing.

   e. Whether defendants had a fiduciary duty to Onyx.

   f. Whether defendants breached a fiduciary duty to Onyx.

   g. Whether defendants' conduct in breaching their fiduciary duty to Onyx was malicious, oppressive, fraudulent or otherwise entitles Onyx to exemplary and punitive damages.

h. Whether Onyx's claims are barred by the statutes of limitations, estoppel, waiver and/or laches.

i. Whether Onyx's claims are barred by its agreement, ratification or acquiescence to the acts and omissions about which it now complains.

j. Whether Onyx's claims are barred by the failure of conditions precedent to Bayer's performance.

k. Whether Onyx's claims are barred by the doctrine of unclean hands.

2. **The principal legal issues that the parties dispute are:**

a. The extent to which a fiduciary duty can be limited by contracts.

b. Whether the "factual issues" listed in the previous section may be issues of law for the Court to decide.

3. **The following issues as to service of process, personal jurisdiction, subject matter jurisdiction, or venue remain unresolved:**

None.

4. **The following parties have not yet been served:**

None.

5. **Any additional parties that a party intends to join are listed below:**

None.

6. **Any additional claims that a party intends to add are listed below:**

None.

C. ALTERNATIVE DISPUTE RESOLUTION (Choose one of the following three options.)

☒ **This case already has been assigned or the parties have agreed to use the following court sponsored or other ADR procedure (please list the provider if other than the court):** Private mediation, with a provider to be determined in further negotiations

Date by which ADR session to be commenced: on or before February 26, 2010

Date by which ADR session to be completed: on or before February 26, 2010

☐ **The parties have been unable to agree on an ADR procedure. The party[ies] listed below believes that the case is appropriate for the ADR procedure indicated:**

☐ **All parties share the view that no ADR procedure should be used in this case. The specific basis for that view is set forth below:**

The parties make the following additional suggestions concerning settlement:

The Court hereby orders:_____

_____

D. CONSENT TO JURISDICTION BY A MAGISTRATE JUDGE

Parties consent to a jury or court trial presided over by a magistrate judge ☐ yes

☒ no

The Court hereby refers this case for the following purposes to a magistrate judge:

_____

_____

E. DISCLOSURES

The parties certify that they have made the following disclosures:

The parties intend to serve their initial disclosures on August 24, 2009.

F. EARLY FILING OF MOTIONS

Neither side currently is preparing to file a motion that is expected to have a significant effect either on the scope of discovery or other aspects of the litigation. Both sides reserve the right to file summary judgment motions before the deadline for doing so.

G. DISCOVERY

1. **The parties have conducted or have underway the following discovery:**

The parties served document requests and interrogatories on August 10, 2009.

2. **The parties have negotiated the following discovery plan:**

The parties have negotiated a discovery plan, as specified elsewhere herein. The parties also are negotiating the terms of a Confidentiality Stipulation and Proposed Protective Order, which will be submitted separately to the Court. The parties also have discussed the form of production of documents, including electronically stored information, and are collaborating on a

Stipulation and Proposed Order Regarding Protocol for Production of Documents and Information, which will be submitted separately to the Court.

3. **Limitations on discovery tools in accordance with Civ. L R. 30-1, 33-1 (specify number):**

a. **depositions (excluding experts) by:**

both sides: 15 (excluding depositions authorized by paragraph 7(b), below)

b. **interrogatories served by:**

both sides: 25

c. **document production requests served by:**

both sides: unlimited

d. **requests for admission:**

The parties agree that each side should be allowed 25 requests for admission regarding substantive issues and a "reasonable" number of requests for admission regarding specific documents for authentication purposes.

4. **The parties agree to the following limitations on the subject matter of discovery:**

a. **Expert communication and drafts of reports.** The parties propose the following limitation on discovery from experts, other than experts (i) who are employees or former employees of a party; and (ii) who have, in connection with their employment by a party (and independent of their service as an expert), performed any work relating to sorafenib or regorafenib: Written communications between counsel and experts, drafts of expert reports and experts' notes shall be non-discoverable in this action, except to the extent that the expert relies upon such communications or notes as the basis for his or her opinion(s) and are not otherwise disclosed in the expert report, its attachments and/or exhibits. The parties and experts (except as noted above) need not retain, produce, or testify about drafts of the expert reports (or related demonstratives or exhibits), other work product prepared by the experts or their staffs, or notes, emails, or other communications made in connection with the drafting of the reports. Oral or

written communications, and notes concerning such communications, between experts (except as noted above) and counsel for the party expecting to call the expert as a witness shall not be discoverable unless the expert is relying on the communication as part of the basis for his or her expert testimony. This stipulation does not apply to underlying materials and documents received by an expert from counsel. Nor does this prevent a party from asking the expert questions in a deposition about the manner in which the expert report was prepared. Notwithstanding the foregoing, drafts of expert reports shall be non-discoverable for any experts (i) who are employees or former employees of a party; and (ii) who have, in connection with their employment by a party (and independent of their service as an expert), performed any work relating to sorafenib or regorafenib.

b. **Privilege logs.** The parties need not list on the privilege log communications with in-house or outside counsel regarding the litigation or issues in the litigation after the commencement of the lawsuit on May 15, 2009.

5. **Discovery from experts. The parties plan to offer expert testimony as to the following subject matter(s):**

a. scientific concepts

b. damages

c. patent issues

6. **The Court orders the following additional limitations on the subject matter of discovery:** _____

_____

_____

_____

7. **Deadlines for disclosure of witnesses and completion of discovery:**

a. **disclosure of identities of all witnesses to be called in each party's case-in-chief:**

both sides: December 23, 2010

b. **completion of all discovery except from experts (see Civ. L.R. 26-5):**

September 30, 2010, except that the parties shall have the right to depose any fact witnesses disclosed pursuant to Section G(7)(a) above who have not previously been deposed in this case. Such depositions shall be completed by January 28, 2011 and shall be limited to twenty (20) hours per side in the aggregate unless extended by agreement of the parties or upon order of the Court upon good cause shown.

c. **disclosure of identities, resumes, final reports and all other matters required by Fed. R. Civ. P. 26(a)(2):**

The parties agree that opening expert reports are due on October 15, 2010, with rebuttal reports due on November 17, 2010. The identity and resume of each expert is due with that expert's earliest report in this matter.

d. **completion of discovery from experts (see Civ. L.R. 26-5):**

December 17, 2010

H. PRETRIAL AND TRIAL SCHEDULE

1. **Trial date:** May 16, 2011
2. **Anticipated length of trial (number of days):** two weeks
3. **Type of trial:** jury
4. **Final pretrial conference date:** April 25, 2011
5. **Date required for filing the joint pretrial conference statement and proposed pretrial order required by Civ. L.R. 16-9(a), complying with the provisions of Civ. L.R. 16-10(b)(7)-(10) and such other materials as may be required by the assigned judge:** March 17, 2011
6. **Date for filing objections under Civ. L.R. 16-10(b)(11) (objections to exhibits or testimony):** April 1, 2011

7. **Deadline to hear motions directed to the merits of all or part of the case:**

February 7, 2011

NOTE: Lead trial counsel who will try this case shall meet and confer at least 30 days prior to the pretrial conference for the purposes of Civ. L.R. 16-9(a) which includes preparation of the joint pretrial conference statement and all other materials required by § H.5 above. Lead trial counsel shall also be present at the pretrial conference. (See Fed. R. Civ. P. 16(e).)

I. Date of next case management status conference: March 8, 2010.

J. OTHER MATTERS

The parties agree that discovery requests, discovery responses and other documents not filed with the Court may be served as PDFs by e-mail, pursuant to Fed. R. Civ. Proc. 5(b)(2)(E).

K. IDENTIFICATION AND SIGNATURE OF LEAD TRIAL COUNSEL

Identify by name, address and phone number lead trial counsel for each party.

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Dated: August 21, 2009

COOLEY GODWARD KRONISH LLP

By: /s/
Martin S. Schenker

Attorney for Plaintiffs
ONYX PHARMACEUTICALS, INC.

Dated: August 21, 2009

By: /s/
Lawrence R. Katzin

Attorney for Defendants
BAYER CORPORATION, BAYER HEALTHCARE LLC , BAYER AG and BAYER SCHERING PHARMA AG

The Court finds that each party was represented by lead trial counsel responsible for trial of this matter and was given an opportunity to be heard as to all matters encompassed by this Case Management Statement and Proposed Order filed prior to this conference.

The foregoing joint statement as amended is adopted by this Court as the Case Management Order in this action in accordance with Civ. L.R. 16 and other applicable Local Rules, and shall govern all further proceedings in this action.

IT IS SO ORDERED.

Dated:_____

_____
Marylyn Hall Patel
United States District Judge

GENERAL ORDER 45 ATTESTATION

In accordance with General Order 45, concurrence in the filing of this document has been obtained from each of the signatories and I shall maintain records to support this concurrence for subsequent production for the Court if so ordered or for inspection upon request by a party.

/s/
Martin S. Schenker

Attorney for Plaintiffs
ONYX PHARMACEUTICALS, INC.